

**Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure**

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Serial No.: 09/966,511

Confirmation No.: 4740

Filed: 28 September 2001

**For: WATER-IN-OIL EMULSIONS WITH ETHYLENE OXIDE GROUPS, COMPOSITIONS, AND METHODS****Remarks**

The Final Office Action mailed 11 February 2004 has been received and reviewed. The pending claims are claims 1-61 and 66-75. Reconsideration and withdrawal of the rejections are respectfully requested.

**Interview Summary Record**

Applicants thank the Examiners for the courtesy extended in an interview on 22 March 2004 between Applicants' Representatives, Ann Mueeting and Nancy Lambert, Examiner Sreeni Padmanabhan, and Examiner Wells. During the interview, Examiner Wells agreed to withdraw the 112, second paragraph rejection. The art rejections were also discussed.

**Information Disclosure Statement**

On February 27, 2002, Applicants submitted an Information Disclosure Statement and 1449 forms to the U.S. Patent and Trademark Office. To date, Applicants have not received an initialed copy of the 1449 forms from the Examiner. Applicants respectfully request that the Examiner initial the 1449 forms and provide a copy to Applicants with the next official communication. For the Examiner's convenience, Applicants enclose herewith a courtesy copy of the 1449 forms submitted on February 27, 2002.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 1-52 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that claims 1, 28, 29, 32, 36, 37, 38, 40, 41, 42, and 48-52 are vague and indefinite because the metes and bounds of the limitation "sparingly soluble" are not ascertainable. In view of the Interview Summary of 22 March 2004, the Examiner indicated that the above rejection will be withdrawn.

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The Examiner rejected claims 1-45, 48-52, and 66-70 under 35 U.S.C. §103(a) as being unpatentable over Michaels (U.S. Patent No. 5,389,676) in view of Kernstock et al. (U.S. Patent No. 4,552,685). The Examiner also rejected claims 46-47 under 35 U.S.C. §103(a) as being unpatentable over Michaels (U.S. Patent No. 5,389,676) in view of Kernstock et al. (U.S. Patent No. 4,552,685) as applied to claims 1-45, 48-52, and 66-70 above, and further in view of Omura et al. (US Patent Publication No. 2003/0064046). These rejections are respectfully traversed.

The Examiner cited Michaels for the disclosure of water-in-oil emulsions and Kernstock et al. for the disclosure of vinyl polymeric thickeners; however, there is no motivation to combine these disclosures. Although both discuss the use of their compositions as shampoos, Michaels discloses both oil-in-water emulsions and water-in-oil emulsions. Furthermore, although the copolymeric thickeners of Kernstock et al. are insoluble in an aqueous liquid at a pH of less than about 2, there is no teaching or suggestion that such polymers could be used in an emulsion (whether it is an oil-in-water or a water-in-oil emulsion).

The Michaels invention is generally directed to an oil-in-water or water-in-oil emulsion containing a unique antiinfective composition comprised of betaine and amine oxide surfactants. Michaels points out that these antiinfective surfactant systems are prone to inactivation of the antiinfective property. See, for example, col. 1, line 63 to col. 2, line 12. Specifically, Michaels avoids the use of several classes of materials to prevent inactivation of his antiinfective surfactant system. These materials include:

- a. Hydrophobic materials with HLB values of greater than 1 and lower than 25 (col. 2, lines 2-5). The oils used in Michaels have HLB values of 1 or less.
- b. Polyethoxylated surfactants such as Brij 78 (col. 1, lines 63-66), POE (5) oleyl ether, and Pluronic F68 (col. 10, lines 54-57).
- c. Compounds containing carboxylate, sulfonate, and sulfate groups such as fatty acids (col. 4, lines 20-25).

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Thus, it is very clear in Michaels that the emulsion aids used must be chosen to prevent inactivation of the antiinfective surfactant system. Therefore, the polymers are chosen from a very narrow class of nonionic, cationic, and amphoteric polymeric emulsion aids that serve to increase viscosity. It is very noteworthy that there are no anionic polymers included, and that of the nonionic polymers disclosed in col. 4 and col. 5, none are polyethoxylated.

Kernstock et al., on the other hand, discloses thickeners for aqueous compositions. The thickeners are comprised of carboxylated and polyethoxylated monomers (see the Abstract, col. 2, line 30 to col. 3, line 15, and col. 5, line 51 to col. 8, line 5). Therefore, one skilled in the art would expect that these would inactivate the Michaels invention.

Also, Kernstock et al. teach making the copolymeric thickeners in water while they are insoluble at low pH values; however, a reasonable interpretation appears that in use they are present in a soluble state. To support this interpretation, the Examiner is requested to note that the compositions of Kernstock et al. are solutions that are to remain clear after the copolymeric thickeners are added (see, e.g., col. 4, lines 11-16). The Examiner is further directed to col. 10, lines 18-24 where Kernstock et al. state: "The pH of the thickened, amphoteric surfactant compositions of this invention is suitably any pH at which the copolymer is soluble or sufficiently swollen to cause thickening without substantially reducing clarity." Hence, the implication is that solutions, as opposed to emulsions, are maintained.

For at least all these reasons, it is respectfully submitted that there is no motivation to combine Michaels with Kernstock et al. That is, there is no motivation to combine the thickeners of Kernstock et al. with the emulsions of Michaels. In fact, Michaels teaches away from this combination.

Finally, with respect to claims 46 and 47, Omura et al. do not provide that which is missing from Michaels and Kernstock et al. Withdrawal of these rejections is respectfully requested.

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It is respectfully submitted that the pending claims 1-61 and 66-75 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

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By

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May 11, 2004

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1<sup>st</sup> day of May, 2004, at 3:42 p.m. (Central Time).

By:

Rachel Gagliardi-Carson

Name:

Rachel Gagliardi-Carson